



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2013-N-0013]

Waivers from Requirements of the Sanitary Transportation of Human and Animal Food Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is publishing three waivers from the requirements of the Sanitary Transportation of Human and Animal Food (the Sanitary Transportation rule). The Agency is taking this action in accord with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The waivers are effective as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael Kashtock, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2022, [Michael.Kashtock@fda.hhs.gov](mailto:Michael.Kashtock@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

### I. Background

In a proposed rule published on February 5, 2014 (79 FR 7006), entitled “Sanitary Transportation of Human and Animal Food,” the Agency announced that it had tentatively determined that, in accordance with the provisions of section 416 (21 U.S.C. 350e) of the FD&C

Act,<sup>1</sup> it would be appropriate to waive the applicable provisions of the rule, if finalized as proposed, with respect to the following classes of persons:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade “A” milk and milk products and
- Food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment.

We requested comment regarding whether these proposed waivers could result in the transportation of food under conditions that would be unsafe for human or animal health, or could be contrary to the public interest. We did not receive any comments with information indicating that these waivers would lead to these outcomes. We published the final rule on April 6, 2016 (81 FR 20091), and established an effective date of June 6, 2016, but did not finalize the proposed waivers at that time, stating that we intended to do so prior to the rule’s initial compliance date of April 6, 2017 (81 FR 20091 at 20106). We are finalizing these waivers through this notification. These waivers are effective upon publication of this notification. In the final rule, we also stated that we would discuss, in a subsequent notice, our thinking on comments we received asking us to consider publishing an additional waiver for transportation operations for molluscan shellfish for entities that hold valid State permits under the National Shellfish Sanitation Program (NSSP) (81 FR 20091 at 20106).

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<sup>1</sup> Section 416(d) of the FD&C Act states that the Secretary of Health and Human Services may waive any requirement under this section, with respect to any class of persons, vehicles, food, or nonfood products, if the Secretary determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and will not be contrary to the public interest.

In response to the proposed rule, we did receive comments requesting that we modify or expand the scope of these waivers beyond that which we discussed in the proposed rule. We received information from an organization representing institutional foodservice establishments that provided details about the operational practices of these establishments relevant to the scope of the proposed waiver.

We have evaluated the comments and information that we received to determine whether we should modify any of the waivers. We have modified the language of the waivers to clarify their applicability only to businesses subject to the requirements of 21 CFR Part 1, Subpart O. We have made a clarification to the Grade “A” milk waiver to specify that it applies to the transportation of bulk and finished Grade “A” milk products. We have also made clarifications to the food establishment waiver to better express the types of businesses within its scope, and to incorporate established definitions in 21 CFR 1.227 to describe the food establishments for which this waiver is available. We have also revised the language of this waiver to make clear that it applies to receiving and delivery operations of a food establishment that are part of the normal business operations of the establishment. In addition, we have modified the language of the food establishment waiver to recognize that State or local authorities may vary in the methods they use to authorize establishments to operate. We have included our analysis of these comments as a reference to this notice (Ref. 1). We also are making this document available at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm>.

In addition, we have evaluated comments we received asking us to consider publishing an additional waiver for certain transportation operations for molluscan shellfish performed by persons that hold valid State permits (meaning that they are appropriately certified) under the NSSP.

Participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, the Environmental Protection Agency, the National Oceanic and Atmospheric Administration, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. The purpose of the program is to promote and improve the sanitation of shellfish (oysters, clams, mussels, and scallops) moving in interstate commerce through Federal/State cooperation and uniformity of State shellfish programs. The NSSP uses as its basic standard the Guide for the Control of Molluscan Shellfish (GCMS), which incorporates a Model Ordinance and related materials (Ref. 2). The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish. Provisions of the GCMS and the NSSP address several aspects of the transportation of molluscan shellfish in interstate commerce including requirements for conveyances, containers used for holding product during transportation, sanitation and temperature control. Through their participation in the NSSP and membership in the Interstate Shellfish Sanitation Conference, states have agreed to enforce the Model Ordinance as the requirements which are minimally necessary for the sanitary control of molluscan shellfish.

The GCMS, and the state regulations modeled after it, specify that every shellstock shipper, i.e., a dealer who grows, harvests, buys, or repacks and sells shellstock (live molluscan shellfish in the shell) shall be certified by a State shellfish control authority or its designated agents. Furthermore, when any requirement of the NSSP is violated, the shipper could be subject to decertification.

We have determined that waiving the requirements of part 1, subpart O, with respect to shippers, loaders, carriers, and receivers who are appropriately certified and inspected under the NSSP, would not result in the transportation of food under conditions that would be unsafe for

human or animal health and would not be contrary to the public interest. Specifically, we have determined that shippers, loaders, carriers, and receivers who are appropriately certified and are inspected under the NSSP, and transport molluscan shellfish in vehicles that are permitted, or otherwise appropriately licensed by the State NSSP certification authority, by complying with requirements that are based upon those set forth in the GCMS, are using sanitary transportation practices to ensure that molluscan shellfish are not transported under conditions that may render such products unsafe.

In accordance with the requirements of section 416 of the FD&C Act, by this notice we are waiving the following persons from the applicable requirements of the Sanitary Transportation rule:

- Businesses subject to the requirements of part 1, subpart O, that hold valid permits and are inspected under the National Conference on Interstate Milk Shipments' Grade "A" Milk Safety Program, only when engaged in transportation operations involving bulk and finished Grade "A" milk and milk products.
- Businesses subject to the requirements of part 1, subpart O, that are permitted or otherwise authorized by the regulatory authority to operate a food establishment that provides food directly to consumers (i.e., restaurants, retail food establishments, and nonprofit food establishments as defined in 21 CFR 1.227), only when engaged in transportation operations as:
  - Receivers, whether the food is received at the establishment itself or at a location where the authorized establishment receives and immediately transports the food to the food establishment;

- shippers and carriers in operations in which food is transported from the establishment as part of the normal business operations of a retail establishment, such as:
  - Delivery of the food directly to the consumer(s) by the authorized establishment or a third-party delivery service or
  - delivery of the food to another location operated by the authorized establishment or an affiliated establishment where the food is to be sold or served directly to the consumer(s).
- Businesses subject to the requirements of part 1, subpart O, that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference's NSSP, only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.

These waivers are effective upon publication of this notification. The issuance of these waivers is deregulatory in nature because they lessen the burden imposed on shippers, receivers, loaders, and carriers engaged in transportation operations without impairing our ability to ensure the safety of food. The waivers will remove certain classes of persons from having to comply with the requirements of part 1, subpart O.

## II. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified

the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Food and Drug Administration Center for Food Safety and Applied Nutrition Analysis of Comments Submitted to Docket FDA 2013-N-0013 Regarding Waivers from the Requirements of 21 CFR Part 1, Subpart O--Sanitary Transportation of Human and Animal Food, March 2017. Available also at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm>.

2. “National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish 2015 Revision”, available at: <http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM505093.pdf>.

Dated: April 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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